

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C. 20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year)

20 July 2000 (20.07.00)

International application No.

PCT/AU99/01052

Applicant's or agent's file reference

2/7388/PC-ME

International filing date (day/month/year)

25 November 1999 (25.11.99)

Priority date (day/month/year)

25 November 1998 (25.11.98)

Applicant

STACEY, Katryn, Jane et al

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

29 May 2000 (29.05.00)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Claudio Borton

Telephone No.: (41-22) 338.83.38

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

FISHER ADAMS KELLY
GPO Box 1413
BRISBANE QLD 4001

- 9 OCT 2000

PCT

NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing
day/month/year

06 OCT 2000

Applicant's or agent's file reference
2/7388/pc

IMPORTANT NOTIFICATION

International application No.
PCT/AU99/01052

International filing date
25 November 1999

Priority date
25 November 1998

Applicant

THE UNIVERSITY OF QUEENSLAND et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translations to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide

Name and mailing address of the IPEA/AU

AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
E-mail address: pct@ipaaustralia.gov.au
Facsimile No. (02) 6285 3929

Authorized officer

MR LEIGH R. TRISTRAM

Telephone No. (02) 6283 2075

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2/7388/pc	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. PCT/AU99/01052	International filing date (<i>day/month/year</i>) 25 November 1999	Priority Date (<i>day/month/year</i>) 25 November 1998
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ G01N 33/566 // C12N 1/68		
Applicant THE UNIVERSITY OF QUEENSLAND et al		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of 4 sheets, including this cover sheet. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of sheet(s).
3. This report contains indications relating to the following items:	
I	<input checked="" type="checkbox"/> Basis of the report
II	<input type="checkbox"/> Priority
III	<input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	<input checked="" type="checkbox"/> Lack of unity of invention
V	<input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	<input type="checkbox"/> Certain documents cited
VII	<input type="checkbox"/> Certain defects in the international application
VIII	<input type="checkbox"/> Certain observations on the international application

Date of submission of the demand	Date of completion of the report
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  MR LEIGH R. TRISTRAM Telephone No. (02) 6283 2075

I. Basis of the report1. With regard to the **elements** of the international application:*

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
 pages , as amended (together with any statement) under Article 19,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the sequence listing part of the description:
 pages , as originally filed
 pages , filed with the demand
 pages , received on with the letter of

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, was on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:

- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

- ☐ complied with.
- ☒ not complied with for the following reasons:

The different inventions identified in the International Search Report are:

1. Claims 1-7, 13-15 (in part) and 18-20(in part)

A method for detecting immunostimulatory DNA based on the complexation of a sample of DNA with an isolated Replication Protein A (RPA) and detection of the complex so formed.

It is considered that the reaction of a DNA sample with isolated RPA and the detection of the complex formed is a first "special technical feature".

2. Claims 8-12, 13-15('m part) and 18-20(in part)

A method for detecting immunostimulatory DNA based on the physical or chemical response of macrophage cells when combined with a sample of DNA 'in the form of either (a) a cell cycle arrest or (b) a reduction in CSF- I receptor (CSFI-R) expression.

It is considered that the measurement of cell cycle arrest or reduction in CSF I -R expression in a macrophage having been combined with a DNA sample is a second "special technical feature".

3. Claims 16 and 17

An immunostimulatory DNA antagonist having one or more phosphorodithioate linkages.

It is considered an immunostimulatory DNA antagonist having one or more phosphorodithioate linkages is a third special technical feature".

It is considered that the abovementioned groups of inventions do not share the same or corresponding special technical features and therefore a "technical relationship" between the inventions, as defined under PCT Rule 13.2 does not exist. Consequently the international application does not relate to one invention or to a single inventive concept.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

- ☐ all parts.
- ☒ the parts relating to claims Nos. 1 - 7, 13 - 15 (in part), 18 - 20 (in part)

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1 - 7, 13 - 15 (in part), 18 - 20 (in part)	YES
	Claims	NO
Inventive step (IS)	Claims 1 - 5, 13 - 15 (in part), 18 - 20 (in part)	YES
	Claims 6, 7	NO
Industrial applicability (IA)	Claims 1 - 7, 13 - 15 (in part), 18 - 20 (in part)	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)**Novelty (N) Claims 1 - 7, 13 - 15 (in part), 18 - 20 (in part)**

The prior art neither discloses nor suggests the method of detecting immunostimulatory DNA or its agonists or antagonists using Replication Protein A, that has been claimed. Consequently the claims are novel.

Inventive Step (IS) Claims 6, 7

Claims 6 and 7 lack inventiveness in the light of :

WOLD, MS., Replication Protein A: a heterotrimeric, single stranded DNA-binding protein required for eukaryotic DNA metabolism", Anu.Rev. Biochem. 1997; 66:61-92.

These claims are directed to a kit that merely comprises the juxtaposition or association of known integers functioning in their normal way and not producing any non-obvious working interrelationship. Thus they are directed to an obvious combination of features not involving an inventive step.

Industrial Applicability (IA) Claims 1 - 7, 13 - 15 (in part), 18 - 20 (in part)

The claims demonstrate industrial applicability.



PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

REC'D 10 OCT 2000

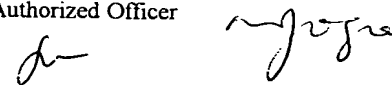
WIPO

PCT

15

Applicant's or agent's file reference 2/7388/pc	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International application No. PCT/AU99/01052	International filing date (day/month/year) 25 November 1999	Priority Date (day/month/year) 25 November 1998
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ G01N 33/566 // C12N 1/68		
Applicant THE UNIVERSITY OF QUEENSLAND et al		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2.	This REPORT consists of a total of 4 sheets, including this cover sheet. <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of sheet(s).
3.	This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input checked="" type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 29 May 2000	Date of completion of the report
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  MR LEIGH R. TRISTRAM Telephone No. (02) 6283 2075

I. Basis of the report**1. With regard to the elements of the international application:***

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
 pages , as amended (together with any statement) under Article 19,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the sequence listing part of the description:
 pages , as originally filed
 pages , filed with the demand
 pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, was on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees the applicant has:
- ☐ restricted the claims.
- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ neither restricted nor paid additional fees.
2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.
- ☒ not complied with for the following reasons:

The different inventions identified in the International Search Report are:

1. Claims 1-7, 13-15 (in part) and 18-20(in part)
A method for detecting immunostimulatory DNA based on the complexation of a sample of DNA with an isolated Replication Protein A (RPA) and detection of the complex so formed.
It is considered that the reaction of a DNA sample with isolated RPA and the detection of the complex formed is a first "special technical feature".
2. Claims 8-12, 13-15('m part) and 18-20(in part)
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It is considered that the measurement of cell cycle arrest or reduction in CSF I -R expression in a macrophage having been combined with a DNA sample is a second "special technical feature".
3. Claims 16 and 17
An immunostimulatory DNA antagonist having one or more phosphorodithioate linkages.
It is considered an immunostimulatory DNA antagonist having one or more phosphorodithioate linkages is a third special technical feature".

It is considered that the abovementioned groups of inventions do not share the same or corresponding special technical features and therefore a "technical relationship" between the inventions, as defined under PCT Rule 13.2 does not exist. Consequently the international application does not relate to one invention or to a single inventive concept.

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:
- ☐ all parts.
- ☒ the parts relating to claims Nos. 1 - 7, 13 - 15 (in part), 18 - 20 (in part)

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1 - 7, 13 - 15 (in part), 18 - 20 (in part)	YES
	Claims	NO
Inventive step (IS)	Claims 1 - 5, 13 - 15 (in part), 18 - 20 (in part)	YES
	Claims 6, 7	NO
Industrial applicability (IA)	Claims 1 - 7, 13 - 15 (in part), 18 - 20 (in part)	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

Novelty (N) Claims 1 - 7, 13 - 15 (in part), 18 - 20 (in part)

The prior art neither discloses nor suggests the method of detecting immunostimulatory DNA or its agonists or antagonists using Replication Protein A, that has been claimed. Consequently the claims are novel.

Inventive Step (IS) Claims 6, 7

Claims 6 and 7 lack inventiveness in the light of :

WOLD, MS., Replication Protein A: a heterotrimeric , single stranded DNA-binding protein required for eukaryotic DNA metabolism", Anu.Rev. Biochem. 1997; 66:61-92.

These claims are directed to a kit that merely comprises the juxtaposition or association of known integers functioning in their normal way and not producing any non-obvious working interrelationship. Thus they are directed to an obvious combination of features not involving an inventive step.

Industrial Applicability (IA) Claims 1 - 7, 13 - 15 (in part), 18 - 20 (in part)

The claims demonstrate industrial applicability.



11

PCTWORLD INTELLECTUAL PROPERTY
International Bureau

NIZATION



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : G01N 33/566 // C12N 1/68	A1	(11) International Publication Number: WO 00/31540 (43) International Publication Date: 2 June 2000 (02.06.00)
(21) International Application Number: PCT/AU99/01052 (22) International Filing Date: 25 November 1999 (25.11.99) (30) Priority Data: PP 7288 25 November 1998 (25.11.98) AU (71) Applicant (for all designated States except US): THE UNIVERSITY OF QUEENSLAND [AU/AU]; St. Lucia, Brisbane, QLD 4072 (AU). (72) Inventors; and (75) Inventors/Applicants (for US only): STACEY, Katryn, Jane [AU/AU]; 24 Highview Terrace, St. Lucia, QLD 4067 (AU). SESTER, David, Peter [AU/AU]; 29 Hawken Drive, St. Lucia, QLD 4067 (AU). SWEET, Matthew, James [AU/GB]; G1 21 Kirkland Street, North Kelvinside, Glasgow, Strathclyde G20 6SY (GB). HUME, David, Arthur [AU/AU]; 27 Aloomba Road, Ashgrove, QLD 4060 (AU). (74) Agent: FISHER ADAMS KELLY; Level 13, AMP Place, 10 Eagle Street, Brisbane, QLD 4000 (AU).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>
(54) Title: IMMUNOSTIMULATORY DNA (57) Abstract Methods of identifying immunostimulatory DNA are provided, which methods include (i) detection of immunostimulatory DNA by formation of a complex between the DNA and isolated Replication Protein A (RPA) subunits; and (ii) down-regulation of CSF-1R expression by macrophages or macrophage cell cycle arrest. Also provided are immunostimulatory DNA agonists and antagonists.		

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
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AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
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BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
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BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
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CM	Cameroon	KR	Republic of Korea	PL	Poland		
CN	China	KZ	Kazakhstan	PT	Portugal		
CU	Cuba	LC	Saint Lucia	RO	Romania		
CZ	Czech Republic	LI	Liechtenstein	RU	Russian Federation		
DE	Germany	LK	Sri Lanka	SD	Sudan		
DK	Denmark	LR	Liberia	SE	Sweden		
EE	Estonia			SG	Singapore		

PATENT COOPERATION TREATY
PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 2/7388/PC-MLE/AL	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/AU 99/01052	International filing date (<i>day/month/year</i>) 25 November 1999	(Earliest) Priority Date (<i>day/month/year</i>) 25 November 1998
Applicant The University of Queensland		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☒ **Unity of invention is lacking** (See Box II).

4. With regard to the **title**, ☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**, ☒ the text is approved as submitted by the applicant

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure

☐ because this figure better characterizes the invention

☒ **None of the figures**

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU 99/01052

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See separate sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1 - 7, 13 - 15 (in part) and 18 - 20(in part)

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

A. CLASSIFICATION OF SUBJECT MATTERInt Cl⁶: G01N 33/566 // C12N 1/68

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC⁶: AS ABOVEDocumentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AS BELOW

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Medline; CAPlus; WPAT

Keywords: immun()stimulat.;RPA,RFA,replication()protein()a,replication()factor()a,DNA()binding()protein,CpG

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WOLD, MS., "Replication protein A: a heterotrimeric, single stranded DNA-binding protein required for eukaryotic DNA metabolism", Anu Rev. Biochem. 1997; 66:61-92	1-20
P,A	PISETSKY, D.S., The influence of base sequence on the immunostimulatory properties of DNA", Immunol. Res., 1999; 19(1):35-46	1-20

☐ Further documents are listed in the continuation of Box C

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"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

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Date of the actual completion of the international search
12 January 2000

Date of mailing of the international search report
18 JAN 2000

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Box II

The different inventions are:

1. Claims 1-7, 13-15 (in part) and 18-20(in part)

A method for detecting immunostimulatory DNA based on the complexation of a sample of DNA with an isolated Replication Protein A (RPA) and detection of the complex so formed.

It is considered that the reaction of a DNA sample with isolated RPA and the detection of the complex formed is a first "special technical feature".

2. Claims 8-12, 13-15(in part) and 18-20(in part)

A method for detecting immunostimulatory DNA based on the physical or chemical response of macrophage cells when combined with a sample of DNA in the form of either (a) a cell cycle arrest or (b) a reduction in CSF-1 receptor (CSF1-R) expression.

It is considered that the measurement of cell cycle arrest or reduction in CSF1-R expression in a macrophage having been combined with a DNA sample is a second "special technical feature".

3. Claims 16 and 17

An immunostimulatory DNA antagonist having one or more phosphorodithioate linkages.

It is considered an immunostimulatory DNA antagonist having one or more phosphorodithioate linkages is a third "special technical feature".

It is considered that the abovementioned groups of inventions do not share the same or corresponding special technical features and therefore a "technical relationship" between the inventions, as defined under PCT Rule 13.2 does not exist. Consequently the international application does not relate to one invention or to a single inventive concept.



INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU 99/01052

A. CLASSIFICATION OF SUBJECT MATTERInt Cl⁶: G01N 33/566 // C12N 1/68

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC⁶: AS ABOVEDocumentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AS BELOW

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

Medline; CAPlus; WPAT

Keywords: immun()(stimulat.;RPA,RFA,replication()protein()a,replication()factor()a,DNA()binding()protein,CpG

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Box 1 Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See separate sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1 - 7, 13 - 15 (in part) and 18 - 20(in part)

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.



1

2

3

4

Box II

The different inventions are:

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It is considered that the measurement of cell cycle arrest or reduction in CSF1-R expression in a macrophage having been combined with a DNA sample is a second "special technical feature".

3. Claims 16 and 17

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It is considered an immunostimulatory DNA antagonist having one or more phosphorodithioate linkages is a third "special technical feature".

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